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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,217	09/23/2003	Robert W. Esmond	4012.0373-02000	2163

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EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1618

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/669,217	Applicant(s) ESMOND ET AL	
	Examiner Vickie Kim	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13,17-19 and 21 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 13,17-19 and 21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/9/2006 & 10/17/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

RCE acknowledged

1. A request for continued examination(RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/9/2006 has been entered.

Status of application

2. All the pending claims 13, 17-19 and 21 were previously indicated as allowable subject matter(2.8.2006). RCE has been filed 8/9/2006 with submission of supplemental IDS which includes several information sheets. **Claims 13, 17-19 and 21 are now pending and presented for the examination.**

Information Disclosure Statement(IDS)

The information disclosure statement (IDS) is submitted on 8/9/2006 and 10/17/2006. Please refer to applicants' copy of the 1449 submitted herewith.

Copy not provided

1. Acknowledgement is made of applicant's remarks submitted with IDS where applicant is informed that the review of the references listed in the instant IDS is done when the references were provided with copending application 09/394712 filed September 13 1999 and the references included in instant IDS has not been submitted with copies. The information disclosure statement filed 8/9/2006 and 10/17/2006 fails to

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comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Since the claimed invention is patentably distinct from the claimed subject matter of copending application 09/394712 and the electronic copy of the references are now available, it is advised to applicant to submit the copies of references for the consideration(see PTO-1449).

Claim Rejections - 35 USC § 112

New Matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The claims 13, 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims 13 and 17-19 are directed to a method for the treatment of Alzheimer's disease using an effective amount of agent to increase insulin sensitivity of the human and restricting the metabolizable carbohydrates in the diet no more than 55

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grams per day wherein the agent is selected from chromium, insulin-like growth factor and a thazolidinedione. The claims are previously indicated as allowable. However, before allowing the claims again, there is one critical error was found in the notice of allowability where the issue has to be raised and clarified to put the patentability of the claims strong and valid before allowing the claims again. The term(i.e. insulin-like growth factor) recited in claim 13 was not described in the specification and lacks the support from the instant disclosure.

The specification discloses a human insulin-like growth factor I(hIGF-I) for making an practicing claimed invention(see page 6, lines 14-22). However, the instant claims are now recite insulin-like growth factor which has broadening the scope and there is no support found in the instant specification for the phrase as an invention at that time of the invention was filed. As mentioned by original specification, human insulin-like growth factor I(hIGF-I) is only growth factor shown proven efficacy against the treatment of Alzheimer disease.

The specification does not provide any competent evidence or disclosed tests for all types of insuline—like growth factors which are instantly claimed and pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, “the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved”(See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)). The specification provides no guidance, in the way of enablement for the full scope of all compounds(i.e. insulin-like growth factor) that are potentially suitable for the invention work similarly as to

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human insulin-like growth factor I. The skill artisan would have not known that which compounds of the claimed compounds are capable of accomplishing the desired result of the claimed invention without undue amount of experimentation.

Thus,

There is no sufficient evidence to convey to one of ordinary skill in the art that applicant was in possession of the claimed invention. Therefore, the claims fail to comply with the written description requirement.

Conclusion

3. No claim is allowed. Claims would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

A large, stylized handwritten signature in black ink, appearing to read 'Vickie Kim', is written over the printed name and title.

Vickie Kim
November 16, 2006
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